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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,067	09/22/2003	Pamela T. Manning	S0 3151/1 US	3024

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 12/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,067	MANNING ET AL.	
	Examiner	Art Unit	
	Leonard M Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Specification

In the abstract, the examiner respectfully points out that it reads: "Methods of treating osteoarthritis by administering **an** therapeutically effective amount of NOS inhibitor are provided."

Double Patenting

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6653350. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are simply broader versions of the claims presented in the patent.

Claim 1 of the current application is drawn to: "A method of modulating IL-1β levels by administering a therapeutic effective amount of an inducible nitric oxide synthase inhibitor to a patient in need thereof."

Claim 1 of U.S. Patent No. 6653350 is drawn to: "A method of modulating IL-1β levels in a patient in need of such modulation comprising administering a therapeutic effective amount of N-iminoethyl-L-lysine to said patient."

Claim 1 of the present application is simply a broader version of claim 1 of US patent No. 6653350 as N-iminoethyl-L-lysine is an inducible nitric oxide synthase inhibitor.

The additional claims of US Patent No. 6653350 are all drawn to N-iminioethyl-L-lysine specifically and the rest of the claims of the present application are simply drawn to a broader group (that includes N-iminoethyl-L-lysine) called "inducible nitric oxide synthase inhibitor".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wahl et al. (U.S. Patent No. 5449688).

Wahl et al., in col. 6 lines 20-35, teach a method of treatment for both acute and chronic inflammation involving administration of therapeutic or effective amount of one or more nitric oxide synthase inhibitors anticipating the "..method of modulating IL-1β levels by administering a therapeutic effective amount of an inducilble nitric oxide synthase inhibitor..." of claim 1, the "...method of modulating osteophyte formation and development in a patient in need thereof by administering a therapeutic effective amount of an inducible nitric oxide synthase inhibitor" of claim 7, and the "..method of modulating metalloproteases by admistering a therapeutic effective amount of an inducible nitric oxide synthase inhibitor..." of claim 13. The examiner respectfully points out that the modulating of IL-1β, osteophyte formation, and metalloproteases by nitric

oxide synthase inhibitors are inherent properties of the inhibitors and thus occur when applied therapeutically.

Wahl et al., in col. 4 lines 1-30, teach specific examples of inflammatory conditions which may be treated by nitric oxide synthase inhibitors including rheumatoid arthritis and osteoarthritis anticipating the "...method of treating osteoarthritis in a patient in need thereof by administering an effective amount of an inducible nitric oxide synthase inhibitor" of claim 11 and that the dose administered should be sufficient to effect a prophylactic or therapeutic response anticipating the "...method of preventing osteoarthritis in a patient in need thereof by administering an effective amount of an inducible nitric oxide synthase inhibitor" of claim 12.

Wahl et al. teach, in col. 4 line 60 to col. 5 line 10 and example 3, L-arginine analogs which inhibit inducible nitric oxide synthase reduce the destructive pathology of chronic inflammation as evidenced by suppression of inflammation, tissue swelling, and bone/cartilage degradation. Additionally, the synovial fluid of the treated arthritic animals exhibited less inflammatory cell infiltrate, less synovial hyperplasia and less evidence of erosions anticipating the "....method of decreasing the amount of synovial fluid..." of claim 2, the "...method of modulating in patient having osteoarthritis the amount of cartilage degeneration ..." of claim 3, the "...method...wherein the severity of said disease is reduced" of claim 4, the "..method...wherein the lesion size is reduced" of claim 5, the "..method...wherein the matrix disorganization of the disease is modified" of claim 6, the "..method of modulating cartilage lesions..." of claim 8, and the

"...method of treating acute joint injury by administering a therapeutic effective amount of an inducible nitric oxide synthase inhibitor..." of claim 14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SHENGJUN WANG
PRIMARY EXAMINER